

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-4 (cancelled).

5 (previously presented). The kit of claim 59 wherein one immunogen is provided which is not any of the following immunogens: a BCG, *Hemophilus influenzae*, *Streptococcus pneumoniae*, hepatitis A, hepatitis B, or *Neisseria* immunogen, or an immunogen of an organism which causes diphtheria, tetanus, pertussis, polio, measles, mumps, rubella, influenza, cholera, plague, varicella, rabies, typhoid or yellow fever.

6 (previously presented). The method of claim 32, wherein for at least one such immunogen, the total dosage during the first 112 days after birth is substantially greater than that required for immunization against the infectious disease with which it is associated.

7 (cancelled).

8 (previously presented). The kit of claim 59 wherein, following such instructions, the first administration is when the mammal is less than 28 days old.

9 (cancelled).

10 (previously presented). The kit of claim 59 wherein, following such instructions, the shortest interval between two successive dosings of at least one immunogen is less than 28 days.

11 (previously presented). The kit of claim 59 wherein, following such instructions during the first 175 days from

birth the longest interval between two successive dosings of at least one immunogen is less than 28 days.

12-15 (cancelled).

16 (previously presented). The kit of claim 59 wherein following such instructions, said mammal is a human.

17-26 (cancelled).

27 (previously presented). A kit for use, prophylactically or therapeutically, to reduce the incidence or severity of a chronic immune mediated disorder, said kit comprising one or more containers, each container holding one or more pharmaceutically acceptable doses of one or more immunogens, said kit further comprising labeling indicating that the kit can be used to reduce the incidence or severity of a chronic immune-mediated disorder in a mammal, and instructions for the prophylactic or therapeutic use of said immunogens to reduce the incidence or severity of a chronic immune-mediated disorder in a mammal to which one or more doses of said immunogens are administered according to an immunization schedule set forth in said instructions, said immunogens, when so administered, acting to substantially reduce the incidence or severity of said chronic immune-mediated disorder, wherein said schedule, according to said instructions, calls for the first dose of an immunogen to be given before 42 days after birth.

28 (previously presented). The kit of claim 27 where if the disorder is diabetes, the diabetes was not streptozotocin-induced.

29 (previously presented). The kit of claim 43 wherein at least one immunogen other than a pertussis immunogen is administered.

30 (previously presented). The kit of claim 16 wherein said kit contains at least one immunogen selected from the group consisting of a *Hemophilus influenzae* immunogen, a BCG immunogen, a hepatitis B immunogen, and an immunogen of an organism which causes a disease selected from the group consisting of diphtheria, tetanus, polio, and pertussis.

31 (cancelled).

32 (previously presented). A method of reducing the incidence or severity of a chronic immune-mediated disorder in a mammal which comprises administering to said mammal one or more immunogens, according to an immunization schedule by virtue of which the mammal receives, at, one or more pharmaceutically acceptable doses of said immunogens, said administrations resulting in an immune response in said mammal which substantially reduces the incidence or severity of at least one chronic immune-mediated disorder in the mammal,

the first dose of said immunization schedule being administered when the mammal is less than 42 days old, measured from birth,

where, if only one immunogen is administered according to said immunization schedule, that immunogen is one other than BCG, and, if said one immunogen is whole cell pertussis, the schedule is one other than a schedule of three doses at one week intervals, all given in the first month,

where, when all of the immunogens administered are selected from the group consisting of a BCG immunogen, *Hemophilus influenzae* immunogen and an immunogen of an organism which causes a disease selected from the group consisting of diphtheria, tetanus, whole cell pertussis, polio, hepatitis B, measles, mumps and rubella, at least one of the following conditions applies: (a) one or more immunogens are

administered on at least three different dates prior to 42 days after birth, or (b) one or more immunogens are administered on at least three different dates, and the maximum interval between administrations is about two weeks, or less.

33 (previously presented). A method of reducing the incidence or severity of an immune disorder in a mammal which comprises administering to said mammal one or more immunogens, according to an immunization schedule by virtue of which the mammal receives, at specific times after birth, one or more pharmaceutically acceptable doses of said immunogens, said administrations resulting in an immune response in said mammal which substantially reduces the incidence or severity of at least one chronic immune-mediated disorder in the mammal, the first dose of said immunization schedule being administered when the mammal is less than 42 days old, measured from birth, where said immunogens are administered from a kit according to claim 27.

34 (previously presented). The kit of claim 27, where said kit is to be used to reduce the incidence or severity of an autoimmune disease, and said labeling so indicates and provides instruction for such use.

35 (previously presented). The kit of claim 27 wherein said labeling states that said kit is to be used to reduce the incidence or severity of systemic lupus erythematosus, and provides instruction for such use.

36 (previously presented). The kit of claim 43, at least one of said immunogens also acting to substantially reduce the incidence or severity of an infectious disease to which said mammal is susceptible, and said labeling so indicates, and provides instruction for such use.

37 (previously presented). The kit of claim 43, which includes at least one immunogen other than a BCG, diphtheria, tetanus, pertussis, polio, hepatitis A, hepatitis B, hemophilus influenza, measles, mumps and rubella, influenza, cholera, BCG, plague, pneumococcus, neisseria, varicella, rabies, typhoid or yellow fever immunogen.

38 (previously presented). The kit of claim 59, wherein, according to said instructions, for at least one such immunogen which elicits an immune response to one of said infectious diseases, the total dosage during the first 112 days after birth is greater than that required for immunization against the infectious disease with which it is associated.

39 (previously presented). The kit of claim 43, wherein, according to said instructions, the first administration when the mammal is less than 28 days old.

40 (previously presented). The kit of claim 27 wherein according to said instructions at least one immunogen is given in two or more dosings such that the shortest interval between two successive dosings thereof is at least one and less than 28 days.

41 (previously presented). The kit of claim 27, wherein according to said instructions at least one immunogen is given in two or more dosings such that the longest interval between two successive dosings thereof is less than 28 days.

42 (cancelled).

43 (previously presented). The kit of claim 28 where the mammal is human.

44 (previously presented). The kit of claim 43 where said kit contains a killed vaccine.

45 (cancelled).

46 (previously presented). The kit of claim 43 where said kit contains a live vaccine.

47-48 (cancelled).

49 (previously presented). The kit of claim 16 where said labeling indicates that starting the first dose of immunization after 56 days after birth may not reduce said chronic immune mediated disorder or may increase the risk of said chronic immune mediated disorder.

50 (previously presented). The kit of claim 43 wherein, following such instructions, the first administration is when the mammal is less than 14 days old.

51 (previously presented). The kit of claim 43 wherein, following such instructions, the first administration is when the mammal is about 7 days old.

52 (previously presented). The kit of claim 27 wherein, following such instructions, the longest interval between two successive dosings is less than or about 14 days.

53-54 (cancelled).

55 (previously presented). The kit of claim 16 in which at least one immunogen is a hemophilus influenza immunogen.

56 (previously presented). A method of reducing the incidence or severity of an immune disorder in a mammal which comprises administering to said mammal one or more immunogens, according to an immunization schedule by virtue of which the mammal receives, at, one or more pharmaceutically acceptable doses of said immunogens, said administrations resulting in an immune response in said mammal which substantially reduces the

incidence or severity of at least one chronic immune-mediated disorder in the mammal,

the first dose of said immunization schedule being administered when the mammal is less than 42 days old, measured from birth,

where, if only one immunogen is administered according to said immunization schedule, that immunogen is one other than BCG, where, when all of the immunogens administered are selected from the group consisting of a BCG immunogen, a *Hemophilus influenzae* immunogen, a hepatitis B immunogen, and an immunogen of an organism which causes a disease selected from the group consisting of diphtheria, tetanus, pertussis, polio, measles, mumps and rubella, at least one of the following conditions applies: (a) one or more immunogens are administered on at least three different dates prior to 42 days after birth, or (b) one or more immunogens are administered on at least three different dates, and the maximum interval between administrations is about two weeks, or less, and where one or more immunogens are administered on at least four different dates.

57 (previously presented). The method of claim 56 where one or more immunogens are administered on at least four different dates during the first 112 days after birth.

58 (cancelled).

59 (previously presented). A kit for use to protect a mammal against an infectious disease to which a mammal is susceptible, said kit comprising one or more containers, each container holding one or more pharmaceutically acceptable doses of one or more immunogens, at least one of said immunogens acting to protect against said infectious disease when appropriately administered to said subject,

said kit comprising labeling containing information

(a) that the kit can be used to reduce the incidence or severity of a chronic immune-mediated disorder in a mammal, and providing instructions for the prophylactic or therapeutic use of said immunogens to reduce the incidence or severity of a chronic immune-mediated disorder in a mammal, said instructions stating that one or more doses should be administered according to an immunization schedule set forth in said instructions, said immunogens, when so administered, acting to substantially reduce the incidence or severity of said chronic immune-mediated disorder,

or

(b) that at least one immunogen of the kit, when administered according to one or more immunization schedules, may, can or does, or has been reported to, increase the incidence or accelerate the onset of a chronic immune-mediated disorder,

or

(c) regarding any animal study or clinical study of the effect of any of said immunogens, or of any immunization schedule for any of said immunogens, on the incidence of a chronic immune-mediated disorder, or on the time of onset of said disorder.

60 (previously presented). The kit of claim 59 where (a) applies.

61 (previously presented). The kit of claim 59 where (b) applies.

62 (previously presented). The kit of claim 61, said labeling further comprising instructions for administering such immunogens so as to avoid such increase in the incidence or severity, or such acceleration in the onset, of said chronic immune-mediated disorder.

63 (previously presented). The kit of claim 59 wherein following such instructions the first administration is when the mammal is less than 14 days old.

64 (previously presented). The kit of claim 59 wherein following such instructions the first administration is at a time from birth to about 7 days after birth.

65 (previously presented). The kit of claim 59 wherein following such instructions the longest interval between two successive dosings is less than or about 14 days.

66 (previously presented). The kit of claim 43 where at least one of said immunogens is a pediatric immunogen.

67 (previously presented) The kit of claim 66 where said pediatric immunogen is selected from the group consisting of a BCG immunogen, a *Hemophilus influenzae* immunogen, a hepatitis B immunogen, and an immunogen which causes a disease selected from the group consisting of measles, mumps, rubella, diphtheria, pertussis, tetanus, and polio.

68 (previously presented). The kit of claim 43 where at least one of said immunogens is a nonpediatric immunogen.

69-70 (cancelled).

71. (previously presented). The kit of claim 43 in which at least one immunogen is selected from the group consisting of a BCG immunogen, a *Hemophilus influenzae* immunogen, and an immunogen of an organism which causes a disease selected from the group consisting of anthrax, plague, tetanus, pertussis, diphtheria, hemophilus influenza and smallpox.

72 (previously presented). The kit of claim 16 where at least one of said immunogens is a pediatric immunogen.

73 (previously presented). The kit of claim 72 where said pediatric immunogen is selected from the group consisting of a BCG immunogen, a *Hemophilus influenzae* immunogen, a hepatitis B immunogen, and an immunogen which causes a disease selected from the group consisting of measles, mumps, rubella, diphtheria, pertussis, tetanus, and polio.

74 (previously presented). The kit of claim 16 where at least one of said immunogens is a nonpediatric immunogen.

75-76 (cancelled).

77 (previously presented). The kit of claim 16 wherein at least one immunogen is selected from the group consisting of a BCG immunogen, a *Hemophilus influenzae* immunogen, and an immunogen of an organism which causes a disease selected from the group consisting of anthrax, plague, tetanus, pertussis, diphtheria, and smallpox.

78 (currently amended). The kit any of claims 59, 60, 61, 62, 96, 97, 30, 49, 55, 74, ~~76~~, 77, 89 90-92, 98-100, 106, 115-117 ~~114-17~~, 125 or 126 in which the disorder is an immune mediated cancer and where said mammal is human.

79 (currently amended). The kit of any of claims 59, 60, 61, 62, 96, 97, 30, 49, 55, 74, ~~76~~, 77, 89 90-92, 98-100, 106, 115-117 ~~114-17~~, 125 or 126 in which the disorder is an autoimmune disease and where said mammal is human.

80 (previously presented). The kit of claim 79 in which the disease is a rheumatic disease or connective tissue disease and where said mammal is human.

81 (currently amended). The kit any of claims 59, 60, 61, 62, 96, 97, 30, 49, 55, 74, ~~76~~, 77, 89 90-92, 98-100, 106, 115-117 ~~114-17~~, 125 or 126 in which the disorder is a neurological disease and where said mammal is human.

82 (previously presented). The kit of claim 81 in which the disease is multiple sclerosis and where said mammal is human.

83 (currently amended). The kit any of claims 59, 60, 61, 62, 96, 97, 30, 49, 55, 74, ~~76~~, 77, ~~89~~ 90-92, 98-100, 106, 115-117 ~~114-17~~, 125 or 126 in which the disorder is asthma and where said mammal is human.

84 (currently amended). The kit any of claims 59, 60, 61, 62, 96, 97, 30, 49, 55, 74, ~~76~~, 77, ~~89~~ 90-92, 98-100, 106, 115-117 ~~114-17~~, 125 or 126 in which the disorder is non-streptozotocin-induced diabetes and where said mammal is human.

85 (currently amended). The kit any of claims 59, 60, 61, 62, 96, 97, 30, 49, 55, 74, ~~76~~, 77, ~~89~~ 90-92, 98-100, 106, 115-117 ~~114-17~~, 125 or 126 in which the disorder is systemic lupus erythematosus and where said mammal is human.

86 (previously presented). The kit of claim 59, said kit further comprising instructions for the use of an immunosuppressant to reduce the incidence or severity of chronic immune mediated disorder which might occur as a result of said administration of said immunogens in the absence of said immunosuppressant.

87 (previously presented). The kit of claim 59 which comprises said immunosuppressant.

88 (previously presented). The kit of claim 86 where said immunosuppressant is a glucocorticoid or a substance which induces the release of a glucocorticoid hormone.

89 (cancelled).

90 (previously presented). The kit of claim 16 in which the disorder is one which develops at least one year after a vaccination.

91 (previously presented). The kit of claim 16 wherein at least one immunogen is a viral immunogen.

92 (previously presented). The kit of claim 16 wherein at least one immunogen is a bacterial immunogen.

93 (previously presented). The kit of claim 59 wherein at least one immunogen is a yeast, mold or plant immunogen.

94 (previously presented). The kit of claim 59 wherein at least one immunogen is an insect immunogen.

95 (previously presented). The kit of claim 59 wherein at least one immunogen is an immunogen of an allogeneic or xenogeneic animal.

96 (previously presented). The kit of claim 61 wherein the labeling indicates that the kit, depending on the immunization schedule according to which one or more of said immunogens is administered, can or does increase the incidence or accelerate the onset of said disorder.

97 (previously presented). The kit of claim 61 wherein the labeling indicates that the kit, depending on the immunization schedule according to which one or more of said immunogens is administered, may, can or does increase the incidence of said disorder.

98 (previously presented). The kit of, claim 16 which includes at least one immunogen other than a pertussis immunogen.

99 (previously presented). The kit of claim 16 which includes at least one immunogen other than a BCG immunogen.

100 (previously presented). The kit of claim 16 where both (a) and (b) apply.

101 (previously presented). The method of claim 32 where at least one of said immunogens elicits an immune response in said mammal which recognizes an immunogen associated with an infectious disease to which said mammal is susceptible.

102 (previously presented). A kit for use, prophylactically or therapeutically, to reduce the incidence or severity of a chronic immune mediated disorder, said kit comprising one or more containers, each container holding one or more pharmaceutically acceptable doses of one or more immunogens, said kit further comprising a label for each container indicating the identity and amount of each immunogen in such container, and labeling indicating that the kit can be used to reduce the incidence or severity of a chronic immune-mediated disorder in a mammal, and instructions for the prophylactic or therapeutic use of said immunogens to reduce the incidence or severity of a chronic immune-mediated disorder in a mammal to which one or more doses of said immunogens are administered according to an immunization schedule set forth in said instructions, said immunogens, when so administered, acting to substantially reduce the incidence or severity of said chronic immune-mediated disorder, wherein said schedule, according to said instructions, calls for the first dose of an immunogen to be given before the subject's immune system arrives at a state of maturation comparable to that achieved at an age of 42 days after birth in a mouse or rat.

103 (previously presented). A method of reducing the incidence or severity of a chronic immune-mediated disorder in

a mammal which comprises administering to said mammal one or more immunogens, according to an immunization schedule by virtue of which the mammal receives, at specific times after birth, one or more pharmaceutically acceptable doses of said immunogens, said administrations resulting in an immune response in said mammal which substantially reduces the incidence or severity of at least one chronic immune-mediated disorder in the mammal,

the first dose of said immunization schedule being administered when the mammal is less than 42 days old, measured from birth,

where said mammal is human, and at least one immunogen other than BCG or pertussis is administered before 42 days after birth.

104 (previously presented). The kit of claim 27 where the mammal is human and the disorder is an autoimmune disease.

105 (previously presented). The kit of claim 59 where the mammal is human and the disorder is an autoimmune disease.

106 (previously presented). The method of claim 103 in which at least one immunogen other than smallpox is administered before 42 days after birth.

107 (previously presented). The kit of claim 27, said kit further comprising a label for each container indicating the identity and amount of each immunogen in such container.

108 (previously presented). The kit of claim 59, said kit further comprising a label for each container indicating the identity and amount of each immunogen in such container.

109 (previously presented). The kit of claim 16 where said labeling indicates that humans with a family history of a

chronic immune-mediated disorder may be at increased risk for developing that disorder after immunization.

110 (previously presented). The kit of claim 16 in which every immunogen is provided other than by a live vaccine.

111 (previously presented). The kit of claim 72 in which every immunogen is provided other than by a live vaccine.

112 (previously presented). The kit of claim 74 in which every immunogen is provided other than by a live vaccine.

113-114 (cancelled).

115 (previously presented). The kit of claim 77 in which every immunogen is provided other than by a live vaccine.

116 (previously presented). The kit of claim 16 which is for use to protect against at least two different infectious diseases, and provides at least one immunogen protecting against each of said diseases.

117 (previously presented). The kit of claim 16 which comprises both at least one pediatric immunogen and at least one non-pediatric immunogen.

118 (previously presented). The kit of claim 16 where said instructions provide for administering the first dose of at least one immunogen on or after 42 days after birth.

119 (previously presented). The kit of claim 16 wherein, according to said instructions, the first administration when the mammal is less than 28 days old.

120 (previously presented). The kit of claim 16 wherein, according to said instructions, the first administration when the mammal is less than 42 days old.

121 (previously presented). The kit of claim 30 where at least one immunogen is selected from the group consisting of a diphtheria, tetanus, polio, hepatitis B and hemophilus influenza B immunogens.

122 (currently amended). The kit of any of claims 66, 67, 68, ~~69, 70~~ or 71 in which every immunogen is provided other than by a live vaccine.

123 (previously presented). The kit of claim 43 wherein said kit contains at least one immunogen selected from the group consisting of a diphtheria, tetanus, polio, Hepatitis B, Hemophilus influenza b, pertussis, and BCG immunogen.

124 (previously presented). The kit of claim 43 wherein said kit contains at least one immunogen selected from the group consisting of diphtheria, tetanus, polio, Hepatitis B, and Hemophilus influenza b immunogens.

125 (previously presented). The kit of claim 43 which is for use to protect against at least two different infectious diseases, and providing at least one immunogen protecting against each of said diseases.

126 (previously presented). The kit of claim 43 which comprises both at least one pediatric immunogen and at least one non-pediatric immunogen.

127 (currently amended). The kit of any of claims 59, 60, 61, 62, 96, 97, 30, 49, 55, 74, ~~76, 77, 89,~~ 91, 92, 98-100, 106-112 or ~~106-117~~ 115-117 in which the disorder is one which develops at least one year after a vaccination.

128 (previously presented). A method of reducing the risk of a chronic immune-mediated disorder associated with immunization to protect against an infectious disease, comprising (1) determining the occurrence of at least one

chronic immune mediated disorder in humans occurring during at least a one year time span after administering an immunogen according to one or more immunization schedules or determining the effect of timing of administering an immunogen on the development of a chronic immune mediated disorder, and (2) providing a kit according to claim 59 comprising at least one of said immunogens and labeling, said labeling indicating that one or more doses of said immunogen can be administered according to more than one immunization schedule or at more than one age set forth in said instructions, said immunogens, when so administered, acting to substantially protect against at least one infectious disease,

where administration according to different immunization schedules may have different effects on the incidence of said chronic immune mediated disorder;

and adhering to said warnings in said instructions may lead to a lower incidence of said chronic immune mediated disorder.

129-143 (cancelled).

144 (previously presented). A method of reducing the incidence or severity of a chronic immune-mediated disorder in a mammal which comprises administering to said mammal one or more immunogens, according to an immunization schedule by virtue of which the mammal receives, at, one or more pharmaceutically acceptable doses of said immunogens, said administrations resulting in an immune response in said mammal which substantially reduces the incidence or severity of at least one chronic immune-mediated disorder in the mammal,

the first dose of said immunization schedule being administered when the mammal is less than 42 days old, measured from birth,

wherein at least one immunogen is provided which is not any of the following immunogens: a BCG, a hepatitis A, a hepatitis B, a *Hemophilus influenzae*, *Streptococcus pneumoniae* or *Neisseria* immunogen, or an immunogen of an organism which causes diphtheria, tetanus, pertussis, polio, measles, mumps, rubella, influenza, cholera, plague, varicella, rabies, typhoid or yellow fever.

145 (previously presented). A method of reducing the incidence or severity of a chronic immune-mediated disorder in a mammal which comprises administering to said mammal one or more immunogens, according to an immunization schedule by virtue of which the mammal receives, at, one or more pharmaceutically acceptable doses of said immunogens, said administrations resulting in an immune response in said mammal which substantially reduces the incidence or severity of at least one chronic immune-mediated disorder in the mammal,

the first dose of said immunization schedule being administered when the mammal is less than 42 days old, measured from birth,

wherein at least one immunogen is administered on at least four different dates prior to 42 days after birth.

146 (previously presented). A method of reducing the incidence or severity of a chronic immune-mediated disorder in a mammal which comprises administering to said mammal one or more immunogens, according to an immunization schedule by virtue of which the mammal receives, at, one or more pharmaceutically acceptable doses of said immunogens, said administrations resulting in an immune response in said mammal which substantially reduces the incidence or severity of at least one chronic immune-mediated disorder in the mammal,

the first dose of said immunization schedule being administered when the mammal is less than 42 days old, measured from birth,

wherein for at least one such immunogen, the total dosage during the first 112 days after birth is greater than that required for immunization against the infectious disease with which it is associated.

147 (previously presented). A method of reducing the incidence or severity of a chronic immune-mediated disorder in a mammal which comprises administering to said mammal one or more immunogens, according to an immunization schedule by virtue of which the mammal receives, at, one or more pharmaceutically acceptable doses of said immunogens, said administrations resulting in an immune response in said mammal which substantially reduces the incidence or severity of at least one chronic immune-mediated disorder in the mammal,

the first dose of said immunization schedule being administered when the mammal is less than 42 days old, measured from birth,

wherein at least one immunogen so administered is one other than pertussis, and a plurality of doses of that immunogen are administered.

148 (previously presented). A method of reducing the incidence or severity of a chronic immune-mediated disorder in a mammal which comprises administering to said mammal one or more immunogens, according to an immunization schedule by virtue of which the mammal receives, at one or more pharmaceutically acceptable doses of said immunogens, said administrations resulting in an immune response in said mammal which substantially reduces the incidence or severity of at least one chronic immune-mediated disorder in the mammal,

the first dose of said immunization schedule being administered before the mammal's immune system arrives at a state of maturation comparable to that achieved at an age of 42 days after birth in a mouse or rat,

where, if only one immunogen is administered according to said immunization schedule, that immunogen is one other than BCG, and, if said one immunogen is whole cell pertussis, the schedule is one other than a schedule of three doses at one week intervals, all given in the first month,

where, when all of the immunogens administered are selected from the group consisting of BCG, diphtheria, tetanus, whole cell pertussis, polio, hepatitis B, hemophilus influenza, measles, mumps and rubella immunogens, at least one of the following conditions applies: (a) one or more immunogens are administered on at least three different dates prior to 42 days after birth, or (b) one or more immunogens are administered on at least three different dates, and the maximum interval between administrations is about two weeks, or less.

149 (previously presented). The kit of claim 68 in which said nonpediatric immunogen is

(a) an immunogen of an organism which causes a disease selected from the group consisting of anthrax, plague, encephalitis, meningitis, typhus, typhoid fever, Lyme disease, cholera, leprosy, varicella, dengue, influenza, herpes, rabies, toxoplasmosis, coccidiomycosis, schistosomiasis and malaria, or

(b) an immunogen selected from the group consisting of *Streptococcus*, *Staphylococcus*, *Neisseria*, *Escherichia coli*, *Shigella*, *Leishmania*, cytomegalovirus (CMV), respiratory syncytial virus, Epstein-Barr virus, herpes virus,

parainfluenza virus, rotavirus, adenovirus, human immunodeficiency virus (HIV), hepatitis A virus And NonA NonB hepatitis virus immunogens.

150 (previously presented). The kit of claim 74 in which said nonpediatric immunogen is

(a) an immunogen of an organism which causes a disease selected from the group consisting of anthrax, plague, encephalitis, meningitis, typhus, typhoid fever, Lyme disease, cholera, leprosy, varicella, dengue, influenza, herpes, rabies, toxoplasmosis, coccidiomycosis, schistosomiasis and malaria, or

(b) an immunogen selected from the group consisting of *Streptococcus*, *Staphylococcus*, *Neisseria*, *Escherichia coli*, *Shigella*, *Leishmania*, cytomegalovirus (CMV), respiratory syncytial virus, Epstein-Barr virus, herpes virus, parainfluenza virus, rotavirus, adenovirus, human immunodeficiency virus (HIV), hepatitis A virus, and NonA NonB hepatitis virus immunogens.

151 (previously presented). The kit of claim 43 in which at least one immunogen is

(a) an immunogen of an organism which causes a disease selected from the group consisting of measles, mumps, rubella, diphtheria, pertussis, tetanus, anthrax, plague, encephalitis, meningitis, pneumonia, typhus, typhoid fever, Lyme disease, cholera, leprosy, influenza, varicella, rabies, dengue, toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria, or

(b) an immunogen selected from the group consisting of BCG, *Hemophilus influenza*, hepatitis B virus, polio virus, *Streptococcus*, *Staphylococcus*, *Neisseria*, *Escherichia coli*,

*Shigella, Leishmania, cytomegalovirus (CMV), respiratory syncytial virus, Epstein-Barr virus, herpes virus, parainfluenza virus, rotavirus, adenovirus, human immunodeficiency virus (HIV), hepatitis A virus, and NonA/NonB hepatitis virus immunogens.*

152 (previously presented). The kit of claim 16 in which at least one immunogen is

(a) an immunogen of an organism which causes a disease selected from the group consisting of measles, mumps, rubella, diphtheria, pertussis, tetanus, anthrax, plague, encephalitis, meningitis, pneumonia, typhus, typhoid fever, Lyme disease, cholera, leprosy, influenza, varicella, rabies, dengue, toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria, or

(b) an immunogen selected from the group consisting of BCG, *Hemophilus influenza*, hepatitis B virus, polio virus, *Streptococcus*, *Staphylococcus*, *Neisseria*, *Escherichia coli*, *Shigella*, *Leishmania*, cytomegalovirus (CMV), respiratory syncytial virus, Epstein-Barr virus, herpes virus, parainfluenza virus, rotavirus, adenovirus, human immunodeficiency virus (HIV), hepatitis A virus, and NonA/NonB hepatitis virus immunogens.

153 (new). A pharmaceutically acceptable immunogenic agent which comprises at least one pediatric and one non-pediatric immunogen,

with the caveat that if there is only one non-pediatric immunogen, the non-pediatric immunogen is one other than a hepatitis A immunogen

where said agent, administered to a human child less than 16 weeks after birth according to an immunization schedule results in protection against at least one infectious disease.

154 (new). A pharmaceutically acceptable immunogenic agent which comprises at least one non-pediatric immunogen,

where at least one such non-pediatric immunogen is a carbohydrate immunogen conjugated to at least one carrier protein,

where administration of one or more dosings of said agent to a human child less than 16 weeks old, according to a first immunization schedule, is associated with protection of that child against at least one infectious disease,

where the administration of at least one such non-pediatric carbohydrate immunogen according to a second immunization schedule, which may be the same as or different from said first immunization schedule, is associated with a decreased risk of development of at least one chronic immune mediated disorder.

155 (new). The agent of claim 154 where said immunogenic agent is monovalent.

156 (new). The agent of claim 154 where said immunogenic agent is divalent.

157 (new). The agent of claim 154 where said immunogenic agent is trivalent.

158 (new). The agent of claim 154 where said immunogenic agent is tetravalent.

159 (new). The agent of claim 154 where said immunogenic agent is pentavalent.

160 (new). The agent of claim 154 where said immunogenic agent is hexavalent.

161 (new). The agent of claim 154 where said immunogenic agent is heptavalent.

162 (new). The agent of claim 154 where said immunogenic agent is at least octavalent.

163 (new). The agent of claim 154 where said immunogenic agent is at least nonavalent.

164 (new). The agent of claim 154 where at least one of said non-pediatric carbohydrate immunogens is a meningococcus immunogen.

165 (new). The agent of claim 154 where at least one of said non-pediatric carbohydrate immunogens is a pneumococcus immunogen.

166 (new). The agent of claim 154 where said immunogenic agent comprises a first non-pediatric carbohydrate immunogen conjugated to a first carrier protein and a second non-pediatric carbohydrate immunogen conjugated to a second and different carrier protein.

167 (new). The agent of claim 154 where said immunogenic agent comprises a unique immunological marker.

168 (new). The agent of claim 154 where said associations are statistically significant

169 (new). The agent of claim 154 where the decreased risk is compared to the risk of chronic immune mediated disorder in such a child if such agent is not administered.

170 (new). The agent of claim 154 where the decreased risk is compared to the risk of chronic immune mediated disorder in such a child if such agent is administered at a different age.

171 (new). The agent of claim 154 which is a monovalent agent comprising a single meningococcus carbohydrate immunogen.

172 (new). The agent of claim 154 which is a divalent agent comprising two different meningoccal carbohydrate immunogens.

173 (new). The agent of claim 154 which is a trivalent agent comprising a plurality of different meningoccal carbohydrate immunogens.

174 (new). The agent of claim 154 which is tetravalent agent comprising a plurality of different meningoccal carbohydrate immunogens.

175 (new). The agent of claim 154 which is a hexavalent agent comprising a plurality of different pneumococcal carbohydrate immunogens.

176 (new). The agent of claim 154 which is a heptavalent agent comprising a plurality of different pneumococcal carbohydrate immunogens.

177 (new). The agent of claim 154 which is an octavalent agent comprising a plurality of different pneumococcal carbohydrate immunogens.

178 (new). The agent of claim 154 which is a nonavalent agent comprising a plurality of different pneumococcal carbohydrate immunogens.

179 (new). The agent of claim 154 where the risk of a chronic immune mediated disorder is determined at least one year after immunization

180 (new). The agent of claim 154 where at least one of said chronic immune mediated disorders is diabetes.

181 (new). The agent of claim 177 Where said immunogenic agent comprises at least two different carrier proteins.

182 (new). The agent of claim 154 where said immunogenic agent is multivalent and one or more non-pediatric carbohydrate immunogens, when either administered alone, with other carbohydrate immunogens, or conjugated to a different carrier was associated with decreased risk of development of a chronic immune mediated disorder.

183 (new). The agent of claim 153 where at least one immunogen is associated with a decreased risk of a chronic immune mediated disorder.

184 (new). The agent of claim 153 where at least one immunogen is associated with an acceptable risk of development of one or more chronic immune mediated disorders.

185 (new). A pharmaceutically acceptable immunogenic agent which comprises at least one non-pediatric immunogen,

where at least one such non-pediatric immunogen is a carbohydrate immunogen conjugated to a carrier protein, where said agent, administered to a human child according to an immunization schedule starting at less than 16 weeks after birth resulting in protection against at least one infectious disease, where the administration of said one or more non-pediatric carbohydrate immunogens is associated with an acceptable risk of development of one or more chronic immune mediated disorders.

186 (new). A pharmaceutically acceptable immunogenic agent which comprises immunogens when administered to a human child according to an immunization schedule starting at less than 16 weeks after birth resulting in adequate protection against at least diphtheria, tetanus, pertussis, where more than one a cellular pertussis immunogens are included, where said agent also comprises at least one more immunogen, where said at least one immunogen is a pediatric immunogen, and where the administration of said at least one immunogen is associated with an acceptable risk of development of one or more chronic immune mediated disorders.

187 (new). The agent according to claim 186 and which is substantially free of immunomodulators, other than immunogens, which are not aluminum or calcium salts or other depot adjuvants.

188 (new). The agent according to claim 187 which is substantially free of aluminum salts.

189 (new). The agent according to claim 186 where said acellular pertussis immunogens are associated with an acceptable risk.

190 (new). The agent of claim 154 where the administration of said agent according to said first immunization schedule is associated with a decreased risk of development of at least one chronic immune mediated disorder.